

Kindly amend the claims as follows.

Claim 10, line 1, replace "9" by --28--.

28 (amended). A method of preparing a pharmaceutical formulation of a lipophilic pharmaceutical active agent in the form of an aqueous nanodispersion, which [comprises] steps consist essentially of

(α) mixing the components

- (a) 0.1 to 30 % by weight of a [membrane-forming molecule] phospholipid,  
(b) 1 to 50 % by weight of a coemulsifier of the polyoxyethylene type,  
(c) 0.1 to 80 % by weight of a lipophilic component which is a natural or synthetic or a partially synthetic C<sub>4</sub>-C<sub>18</sub>[di-or]triglyceride, [a mineral oil, silicone oil, wax, fatty alcohol, guerbet alcohol or the ester thereof, a therapeutic oil,] and a lipophilic pharmaceutical active agent [or a mixture of these substances], in which [the lipophilic] any pharmaceutically active agent is lipophilic and is always present as component (c), and  
(d) 0.63 to 14.2 % by weight of [a C<sub>2</sub>-C<sub>8</sub>alcohol] ethanol

in conventional stirring apparatus until a homogeneous clear liquid is obtained and

(β) adding the liquid obtained in step (α) to the water phase, wherein (β) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter <50 nm.

29 (amended). An aqueous nanodispersion of a lipophilic pharmaceutical active agent, which [comprises] consists essentially of

- (a) 0.1 to 30 % by weight of a [membrane-forming molecule] phospholipid,  
(b) 1 to 50 % by weight of a coemulsifier of the polyoxyethylene type,  
(c) 0.1 to 80 % by weight of a lipophilic component which is a natural or synthetic or a partially synthetic C<sub>4</sub>-C<sub>18</sub>[di-or]triglyceride, [a mineral oil, silicone oil, wax, fatty alcohol, guerbet alcohol or the ester thereof, a therapeutic oil,] and a lipophilic pharmaceutical active agent [or a mixture of these substances], in which [the lipophilic] any pharmaceutically active agent is lipophilic and is always present as component (c), and  
(d) 0.63 to 14.2 % by weight of [a C<sub>2</sub>-C<sub>8</sub>alcohol] ethanol, with the proviso that the sum of (a), (b), (c) and (d) is 100 % by weight, plus  
(e) a water phase,

which formulation is obtainable by

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(α) mixing the components (a), (b), (c), and (d) until a homogeneous clear liquid is obtained, and  
(β) adding the liquid obtained in step (α) to a water phase, wherein step (β) is carried out in the absence of high shear or cavitation forces, and whereby the particles in the nanodispersion have an average diameter <50 nm.

### STATUS OF THE CLAIMS

Claims 2, 5-6, 9-10, 12, 15-21, 24, 28 and 29 were pending in this application.

Claims 16-17, 20-21 and 29 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,171,566 (Mizushima).

Claim 29 is rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent 5,338,761 (Nakajima et al.).

Claims 2, 5-6, 9-10, 15-21, 24 and 28-29 are rejected under 35 U.S.C. § 102 as being anticipated, or in the alternative as obvious over U.S. Patent 5,633,226 (Owen et al.).

Claims 2, 5-6, 9-10, 15-21, 24 and 28-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 95/16441.

Claims 5 and 9 have been cancelled.

Claims 10, 28 and 29 have been amended.

Claims 2, 6, 10, 15-21, 24 and 28-29 are presented for reconsideration.

### REMARKS

Applicants note with appreciation a telephonic interview wherein the examiner confirmed that applicants' remarks were persuasive and that the claims rejection under 35 U.S.C. § 112, first paragraph (head note 1) had been withdrawn.